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Pesticide Fact Sheet Number 15: Chlorobenzilate

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, Science Findings

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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Washington, DC 20460

EPA

Pesticide Fact Sheet

Name of Chemical: CHLOROBENZILATE
Reason for Issuance:
Date Issued: December 30, 1983
Fact Sheet Number: 15

1. Description of the chemical:

- Generic name: ethyl 4,4'-dichlorobenzilate
- Common name: Chlorobenzilate
- Trade name: Acaraben
- EPA Shaughnessy Code: 028801
- Chemical abstracts services number: 510-15-6
- Year of initial registration: 1953
- Pesticide type: Miticide
- Chemical family: Organochlorine compound
- U.S. and Foreign producers: Ciba-Geigy, Nippon Kayaku, Japan and Makhteshim Beer-Sheva, Israel

2. Use patterns and formulations:

- Application sites: Citrus
- Types of formulations: Four pound per gallon emulsifiable concentrate
- Types and Methods of Application: Aerial and ground foliar sprays restricted to citrus use only in the states of Arizona, California, Florida and Texas for control of mites
- Application rates: 0.75 lb/ acre
- Usual carriers: water

3. Science findings:

Summary of Science Statement:

- Chlorobenzilate is classified RESTRICTED.

- Chlorobenzilate met criteria for unreasonable adverse effects due to the oncogenicity "trigger".

- Chlorobenzilate is suspected to be contaminated by DDT and/or its analogs at or near the limit of detection (by Thin Layer Chromatography). The Agency is requesting registrants to do further analyses with more sensitive analytical techniques to search for these impurities.

Chemical charcteristics:

- Chlorobenzilate, an organochlorine compound, is a brownish viscous liquid with boiling and melting points of 141-142 °C and 35-37 °C, respectively. The chemical is virtually insoluble in water and stable at room temperature.

Toxicological characteristics:

- Overall toxicity category III
- Acute Oral LD_{50} - 960 to 1220 mg/kg - Category III
- Acute Dermal LD_{50} - greater than 10,200 mg/kg- Category IV
- Acute Inhalation LC_{50} - Data Gap
- Primary Eye Irritation- Rabbit- Data Gap
- Primary Dermal Irritation - Data Gap
- Dermal Sensitization- Data Gap
- The major routes of exposure are believed to be dermal followed by inhalation.

-Chronic toxicity results:
The chemical is an oncogen.
Data gaps include, teratology and mutagenicity testing.
Using the protective clothing and the use restriction limited to citrus as required in the Rebuttable Presumption Against Registration, the lifetime oncogenicity risk would be between 0.5 and 7.0×10^{-6} from dietary exposure and between 65 and 190 x 10^{-6} from applicator exposure. A risk-benefits analysis of this use pattern indicates the benefits derived from this use outweighes the risks involved.

Physiological and Biochemical Behavioral Characteristics:

-Foliar absorption remains a data gap.
-Metabolism and persistence in plants and animals are data gsps.
-Pesticidal action: nerve poison.

Ecological characteristics:

- No data available. Most studies reserved pending review of basic product chemistry, environmental fate, toxicology and residue chemistry data. Potential problems related to endangered species are unknown.

Environmental characteristics:

- An environmental assessment can not be made at this time because there is a lack of the data needed to make this assessment.

Tolerance Assessment:

- Because all uses of chlorobenzilate are cancelled except citrus, a recalculation of the Theoretical Maximum Residue Concentration (TMRC), Acceptable Daily Intake (ADI), and Maximum Permissible Intake (MPI) was undertaken. These values are 0.2859 mg/day/1.5 kg (3.81% of the ADI), 0.125 mg/kg/day and 7.50 mg/day/60 kg, respectively. These values are considered provisional at this time. Another reassessment and recalculation of the ADI/MPI will be made when the toxicology data gaps are filled.

- A food additive tolerance(s) is required for citrus oil.

- Established tolerances other than citrus and the associated meat, fat and meat byproducts will be revoked in 1984 because all other uses were cancelled by the RPAR action.

4. Summary of Regulatory Position and Rationale:

- An interim 24-hour reentry interval on citrus crops has been established until the Agency receives reentry data.

- The Agency will make a determination as to the continued registrability of this chemical when the data requested in the Registration Standard Guidance Document is submitted and reviewed.

- The Agency determined in the Special Review process that chlorobenzilate end-use products be classified as "Restricted Use" to reduce exposure to loaders, mixers and applicators. The chemical will continue to be classified for "Restricted Use" until the Agency receives data to reevaluate its position.

- The Agency has concluded, via the Special Review process, that by limiting the use of chlorobenzilate to citrus, classifying chlorobenzilate products for restricted use, and upgrading the protective clothing requirements, the exposure level and risk would be lowered to acceptable levels. The benefits are determined to exceed the risks and the chemical is allowed continued registration, provided the following data are submitted and they do not suggest new unacceptable toxicological and/or environmental properties of chlorobenzilate.

5. Summary of Data Gaps:

The following data gaps were required to be submitted by January of 1987.

- Mutagenicity testing
- Rat inhalation LC_{50} study
- Primary eye irritation study (rabbit)
- Primary dermal irritation study
- Dissipation studies
- Mobility studies
- Hydrolysis studies
- Aerobic soil metabolism study
- photodegradation studies
- Fish accumulation studies
- Avian oral LD_{50} testing
- Avian dietary LC_{50}
- Avian reproduction studies
- Freshwater fish LC_{50}
- Acute LC_{50} freshwater invertebrates study
- Acute LC_{50} estuarine and marine organisms study
- Fish early life stage and aquatic invertebrate life-cycle study
- Fish life-cycle study

These data gaps are required to be submitted by April of 1984

- Identity of Ingredients
- Statement of Composition
- Discussion of Formation of Ingredients
- Preliminary Analysis
- Certification of Limits
- Analytical Methods for Enforcement of Limits
- Physical and Chemical Characteristics (except melting point & pH)

Teratology study- 2 species by October of 1984
Citrus Fractionation Study- Feb. of 1984 (promised April 1, 1984)
Feeding Citrus By-Products to Cattle- Feb. of 1984 (promised April 1, 1984)
Aerial Applicators Study- Feb. of 1984 (received March, 1984)
Citrus Picker Exposure Study- Feb. of 1984 (received March, 1984)

6. Contact person at EPA

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